



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, New York 11433-1034

WARNING LETTER

January 29, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

REF: NYK-2001-38

Allen Rothpearl
Administrator
Elmont Open MRI
545 Elmont Road
Elmont, New York 11003

Facility ID: #220442

Dear Mr. Rothpearl:

Your facility was inspected on December 14th, 2000, by a representative of the Nassau County Department of Health, Office of Radiological Health acting on behalf of the U. S. Food & Drug Administration (FDA). We apologize for the delay in agency review of the noncompliances noted during this inspection. This inspection has revealed a serious regulatory problem involving the mammography operations at your facility. Under a United States Federal Law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for conducting a mammography operation. These requirements help protect the health of women by assuring that a facility can perform quality mammography procedures. The inspection revealed the following repeat Level 2 noncompliance finding at your facility:

1. *The Interpreting Physician [REDACTED] did not meet the continuing education requirement of having completed a minimum of fifteen (15) CME credits in mammography in a 36 month period.*

The specific problem noted above appeared on your MQSA Facility Inspection Report which was issued to your facility at the close of the inspection. This problem is identified as a repeat Level 2 noncompliance, because it identifies a failure to meet a significant MQSA requirement and indicates failure by your facility to implement correction of problems found during your previous inspection.

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Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography operations and service at your facility, it represents a violation of the law which may result in *FDA* taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography operations.

There was also a repeat Level 3 noncompliance finding that was listed on the inspection report provided at the close of the inspection. The repeat Level 3 noncompliance finding was:

- 1. The required personnel qualification documents were unavailable during the inspection.*

This acknowledges receipt of the response letter dated January 11th, 2001 (attached) received from [REDACTED], regarding the inspection referenced herein. We have the following comments concerning this response:

- 1. We wish to emphasize that the Interpreting Physician, Dr. [REDACTED] cannot conduct independent mammography operations until he has completed the fifteen (15) CME credit requirement.*
- 2. Your written response also fails to address the issue of the missing personnel qualification records.*

It is necessary for you to act on these matters immediately. Please explain to this office in writing within fifteen (15) working days from the date you receive this letter:

- The specific steps you have taken to correct the violations noted in this letter;*
- Each step your facility is taking to prevent the recurrence of similar violations; and*
- Sample records that demonstrate proper record keeping procedures.*

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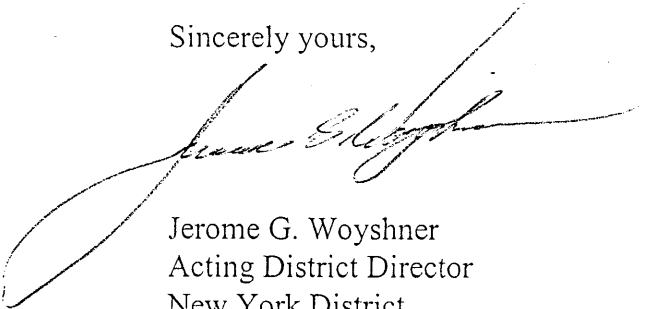
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Please submit your response to the above issues to the attention of Arthur S. Williams, Jr., Compliance Officer, U. S. Food & Drug Administration (FDA), 158 - 15 Liberty Avenue, Jamaica, New York 11433-1034, Tel.: (718)/662-5568.

Finally, you should understand there are many FDA requirements pertaining to mammography operations and procedures. This letter pertains only to the findings of our inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, U. S. Food & Drug Administration (FDA), P.O. Box 6057, Columbia, Maryland 21045-6057, Tel. (1-800/838-7715), or through the Internet at <http://www.fda.gov>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jerome G. Woyshner", is written over a large, stylized, looping flourish that extends from the left side of the signature area.

Jerome G. Woyshner
Acting District Director
New York District